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APPLICATION NUMBER: 60/507,688
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RELATED PCT APPLICATION NUMBER: *PCT/US04/32025*

Certified by



Jon W Dudas

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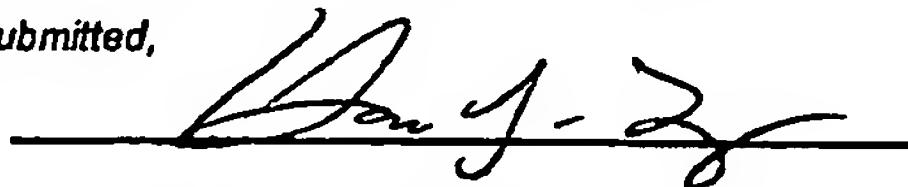
22 54 U.S. PTO
60/507688

09/30/03

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<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
METHOD AND APPARATUS FOR ELASTOMER BASED ACTUATOR					
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<input type="checkbox"/> Firm or Individual Name		Heller Ehrman White & McAuliffe, L.L.P.			
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City		Menlo Park	State	CA	ZIP 94025-3506
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification		Number of Pages	13	<input type="checkbox"/> CD(s), Number	
<input checked="" type="checkbox"/> Drawing(s)		Number of Sheets	8	<input checked="" type="checkbox"/> Other (specify)	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76		Return postcard APPLICATION COVER SHEET			
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE AMOUNT (\$)	
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number.		08-1641		\$80.00	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
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<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

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Date

09/30/2003

REGISTRATION NO.

(if appropriate)

Docket Number:

43,209

38187-2697

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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PROVISIONAL PATENT APPLICATION
METHOD AND APPARATUS FOR ELASTOMER BASED
ACTUATOR

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METHOD AND APPARATUS FOR ELASTOMER BASED ACTUATOR

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BACKGROUND OF THE INVENTION

Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. The device may be held against the skin and mechanically triggered to ballistically launch the lancet. Unfortunately, the pain associated with each lancing event using known technology discourages patients from testing. In addition to vibratory stimulation of the skin as the driver impacts the end of a launcher stop, known spring based devices have the possibility of firing lancets that harmonically oscillate against the patient tissue, causing multiple strikes due to recoil. This recoil and multiple strikes of the lancet is one major impediment to patient compliance with a structured glucose monitoring regime.

Success rate generally encompasses the probability of producing a blood sample with one lancing action, which is sufficient in volume to perform the desired analytical test. The blood may appear spontaneously at the surface of the skin, or may be "milked" from the wound. Milking generally involves pressing the side of the digit, or in proximity of the wound to express the blood to the surface. In traditional methods, the blood droplet produced by the lancing action must reach the surface of the skin to be viable for testing.

When using existing methods, blood often flows from the cut blood vessels but is then trapped below the surface of the skin, forming a hematoma. In other instances, a wound is created, but no blood flows from the wound. In either case, the lancing process cannot be combined with the sample acquisition and testing step. Spontaneous blood droplet generation with current mechanical launching system varies between launcher

30

types but on average it is about 50% of lancet strikes, which would be spontaneous. Otherwise milking is required to yield blood. Mechanical launchers are unlikely to provide the means for integrated sample acquisition and testing if one out of every two strikes does not yield a spontaneous blood sample. It would be desirable to find improved
5 methods to actuate the lancet.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. The invention relates to the electronically controlled actuation of a
10 lancet to create a wound for the collection of a blood sample for analysis. Specifically, some embodiments of the present invention provide an improved fluid sampling device. Because of the obtain spontaneous blood generation in a relatively painless manner, the ability to move the penetrating member at a high, yet controllable velocity is of interest. At least some of these and other objectives described herein will be met by embodiments
15 of the present invention.

In one aspect of the present invention, the invention relates to using the electronic tissue penetration device to drive a penetrating member into tissue, wherein an elastomeric portion actuated by the electronic device to drive the penetrating member. More specifically, the invention relates to the electronic actuation of a lancet through the use of
20 an elastomeric capacitor that can be made to change length with the application of voltage across the capacitor plates.

In one embodiment, a method of body fluid sampling is provided. The method comprises moving a penetrating member at conforming to a selectable velocity profile or motion waveform by using electricity to actuate an elastomeric device and measuring
25 the position of the penetrating member. In some embodiments, the device will use the position data to create a feedback loop wherein the actuator will move the penetrating member at velocities that follow a desired trajectory.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for improving spontaneous blood generation. The invention may use a high density penetrating member design. It may use penetrating members of smaller size, such as but not limited to diameter or length, than those of conventional penetrating members known in the art. The device may be used for multiple lancing events without having to remove a disposable from the device. The invention may provide improved sensing capabilities. At least some of these and other objectives described herein will be met by embodiments of the present invention.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms “a”, “an” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to “a material” may include mixtures of materials, reference to “a chamber” may include multiple chambers, and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

“Optional” or “optionally” means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

The present invention may be used with a variety of different penetrating member drivers. It is contemplated that these penetrating member drivers may be spring based, solenoid based, magnetic driver based, nanomuscle based, or based on any other mechanism useful in moving a penetrating member along a path into tissue. It should be noted that the present invention is not limited by the type of driver used with the penetrating member feed mechanism. One suitable penetrating member driver for use with the present invention is shown in Figure 1. This is an embodiment of a solenoid type

electromagnetic driver that is capable of driving an iron core or slug mounted to the penetrating member assembly using a direct current (DC) power supply. The electromagnetic driver includes a driver coil pack that is divided into three separate coils along the path of the penetrating member, two end coils and a middle coil. Direct current
 5 is alternated to the coils to advance and retract the penetrating member. Although the driver coil pack is shown with three coils, any suitable number of coils may be used, for example, 4, 5, 6, 7 or more coils may be used.

Referring to the embodiment of Figure 1, the stationary iron housing 10 may contain the driver coil pack with a first coil 12 flanked by iron spacers 14 which
 10 concentrate the magnetic flux at the inner diameter creating magnetic poles. The inner insulating housing 16 isolates the penetrating member 18 and iron core 20 from the coils and provides a smooth, low friction guide surface. The penetrating member guide 22 further centers the penetrating member 18 and iron core 20. The penetrating member 18 is protracted and retracted by alternating the current between the first coil 12, the middle
 15 coil, and the third coil to attract the iron core 20. Reversing the coil sequence and attracting the core and penetrating member back into the housing retracts the penetrating member. The penetrating member guide 22 also serves as a stop for the iron core 20 mounted to the penetrating member 18.

As discussed above, tissue penetration devices which employ spring or cam
 20 driving methods have a symmetrical or nearly symmetrical actuation displacement and velocity profiles on the advancement and retraction of the penetrating member as shown in Figures 2 and 3. In most of the available lancet devices, once the launch is initiated, the stored energy determines the velocity profile until the energy is dissipated. Controlling impact, retraction velocity, and dwell time of the penetrating member within
 25 the tissue can be useful in order to achieve a high success rate while accommodating variations in skin properties and minimize pain. Advantages can be achieved by taking into account of the fact that tissue dwell time is related to the amount of skin deformation as the penetrating member tries to puncture the surface of the skin and variance in skin deformation from patient to patient based on skin hydration.

30 In this embodiment, the ability to control velocity and depth of penetration may be achieved by use of a controllable force driver where feedback is an integral part of driver control. Such drivers can control either metal or polymeric penetrating members or any other type of tissue penetration element. The dynamic control of such a driver is

illustrated in Figure. 2C which illustrates an embodiment of a controlled displacement profile and Figure 2D which illustrates an embodiment of a the controlled velocity profile. These are compared to Figures 2A and 2B, which illustrate embodiments of displacement and velocity profiles, respectively, of a harmonic spring/mass powered driver. Reduced pain can be achieved by using impact velocities of greater than about 2 m/s entry of a tissue penetrating element, such as a lancet, into tissue. Other suitable embodiments of the penetrating member driver are described in commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-2551) filed April 19, 2002 and previously incorporated herein.

Figure 3 illustrates the operation of a feedback loop using a processor 60. The processor 60 stores profiles 62 in non-volatile memory. A user inputs information 64 about the desired circumstances or parameters for a lancing event. The processor 60 selects a driver profile 62 from a set of alternative driver profiles that have been preprogrammed in the processor 60 based on typical or desired tissue penetration device performance determined through testing at the factory or as programmed in by the operator. The processor 60 may customize by either scaling or modifying the profile based on additional user input information 64. Once the processor has chosen and customized the profile, the processor 60 is ready to modulate the power from the power supply 66 to the penetrating member driver 68 through an amplifier 70. The processor 60 may measure the location of the penetrating member 72 using a position sensing mechanism 74 through an analog to digital converter 76 linear encoder or other such transducer. Examples of position sensing mechanisms have been described in the embodiments above and may be found in the specification for commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-2551) filed April 19, 2002 and previously incorporated herein. The processor 60 calculates the movement of the penetrating member by comparing the actual profile of the penetrating member to the predetermined profile. The processor 60 modulates the power to the penetrating member driver 68 through a signal generator 78, which may control the amplifier 70 so that the actual velocity profile of the penetrating member does not exceed the predetermined profile by more than a preset error limit. The error limit is the accuracy in the control of the penetrating member.

After the lancing event, the processor 60 can allow the user to rank the results of the lancing event. The processor 60 stores these results and constructs a database 80 for

the individual user. Using the database 79, the processor 60 calculates the profile traits such as degree of painlessness, success rate, and blood volume for various profiles 62 depending on user input information 64 to optimize the profile to the individual user for subsequent lancing cycles. These profile traits depend on the characteristic phases of penetrating member advancement and retraction. The processor 60 uses these calculations to optimize profiles 62 for each user. In addition to user input information 64, an internal clock allows storage in the database 79 of information such as the time of day to generate a time stamp for the lancing event and the time between lancing events to anticipate the user's diurnal needs. The database stores information and statistics for each user and each profile that particular user uses.

In addition to varying the profiles, the processor 60 can be used to calculate the appropriate penetrating member diameter and geometry suitable to realize the blood volume required by the user. For example, if the user requires about 1-5 microliter volume of blood, the processor 60 may select a 200 micron diameter penetrating member to achieve these results. For each class of lancet, both diameter and lancet tip geometry, is stored in the processor 60 to correspond with upper and lower limits of attainable blood volume based on the predetermined displacement and velocity profiles.

The lancing device is capable of prompting the user for information at the beginning and the end of the lancing event to more adequately suit the user. The goal is to either change to a different profile or modify an existing profile. Once the profile is set, the force driving the penetrating member is varied during advancement and retraction to follow the profile. The method of lancing using the lancing device comprises selecting a profile, lancing according to the selected profile, determining lancing profile traits for each characteristic phase of the lancing cycle, and optimizing profile traits for subsequent lancing events.

Figure 4 illustrates an embodiment of a tissue penetration device, more specifically, a lancing device 80 that includes a controllable driver 179 coupled to a tissue penetration element. The lancing device 80 has a proximal end 81 and a distal end 82. At the distal end 82 is the tissue penetration element in the form of a penetrating member 83, which is coupled to an elongate coupler shaft 84 by a drive coupler 85. The elongate coupler shaft 84 has a proximal end 86 and a distal end 87. A driver coil pack 88 is disposed about the elongate coupler shaft 84 proximal of the penetrating member 83. A position sensor 91 is disposed about a proximal portion 92 of the elongate coupler shaft

84 and an electrical conductor 94 electrically couples a processor 93 to the position sensor 91. The elongate coupler shaft 84 driven by the driver coil pack 88 controlled by the position sensor 91 and processor 93 form the controllable driver, specifically, a controllable electromagnetic driver.

5 Referring to Figure 5, the lancing device 80 can be seen in more detail, in partial longitudinal section. The penetrating member 83 has a proximal end 95 and a distal end 96 with a sharpened point at the distal end 96 of the penetrating member 83 and a drive head 98 disposed at the proximal end 95 of the penetrating member 83. A penetrating member shaft 201 is disposed between the drive head 98 and the sharpened point 97. The
10 penetrating member shaft 201 may be comprised of stainless steel, or any other suitable material or alloy and have a transverse dimension of about 0.1 to about 0.4 mm. The penetrating member shaft may have a length of about 3 mm to about 50 mm, specifically, about 15 mm to about 20 mm. The drive head 98 of the penetrating member 83 is an enlarged portion having a transverse dimension greater than a transverse dimension of the
15 penetrating member shaft 201 distal of the drive head 98. This configuration allows the drive head 98 to be mechanically captured by the drive coupler 85. The drive head 98 may have a transverse dimension of about 0.5 to about 2 mm.

A magnetic member 102 is secured to the elongate coupler shaft 84 proximal of the drive coupler 85 on a distal portion 203 of the elongate coupler shaft 84. The
20 magnetic member 102 is a substantially cylindrical piece of magnetic material having an axial lumen 204 extending the length of the magnetic member 102. The magnetic member 102 has an outer transverse dimension that allows the magnetic member 102 to slide easily within an axial lumen 105 of a low friction, possibly lubricious, polymer guide tube 105' disposed within the driver coil pack 88. The magnetic member 102 may
25 have an outer transverse dimension of about 1.0 to about 5.0 mm, specifically, about 2.3 to about 2.5 mm. The magnetic member 102 may have a length of about 3.0 to about 5.0 mm, specifically, about 4.7 to about 4.9 mm. The magnetic member 102 can be made from a variety of magnetic materials including ferrous metals such as ferrous steel, iron, ferrite, or the like. The magnetic member 102 may be secured to the distal portion 203 of
30 the elongate coupler shaft 84 by a variety of methods including adhesive or epoxy bonding, welding, crimping or any other suitable method.

Proximal of the magnetic member 102, an optical encoder flag 206 is secured to the elongate coupler shaft 84. The optical encoder flag 206 is configured to move within

a slot 107 in the position sensor 91. The slot 107 of the position sensor 91 is formed between a first body portion 108 and a second body portion 109 of the position sensor 91. The slot 107 may have separation width of about 1.5 to about 2.0 mm. The optical encoder flag 206 can have a length of about 14 to about 18 mm, a width of about 3 to about 5 mm and a thickness of about 0.04 to about 0.06 mm.

The optical encoder flag 206 interacts with various optical beams generated by LEDs disposed on or in the position sensor body portions 108 and 109 in a predetermined manner. The interaction of the optical beams generated by the LEDs of the position sensor 91 generates a signal that indicates the longitudinal position of the optical flag 206 relative to the position sensor 91 with a substantially high degree of resolution. The resolution of the position sensor 91 may be about 200 to about 400 cycles per inch, specifically, about 350 to about 370 cycles per inch. The position sensor 91 may have a speed response time (position/time resolution) of 0 to about 120,000 Hz, where one dark and light stripe of the flag constitutes one Hertz, or cycle per second. The position of the optical encoder flag 206 relative to the magnetic member 102, driver coil pack 88 and position sensor 91 is such that the optical encoder 91 can provide precise positional information about the penetrating member 83 over the entire length of the penetrating member's power stroke.

An optical encoder that is suitable for the position sensor 91 is a linear optical incremental encoder, model HEDS 9200, manufactured by Agilent Technologies. The model HEDS 9200 may have a length of about 20 to about 30 mm, a width of about 8 to about 12 mm, and a height of about 9 to about 11 mm. Although the position sensor 91 illustrated is a linear optical incremental encoder, other suitable position sensor embodiments could be used, provided they possess the requisite positional resolution and time response. The HEDS 9200 is a two channel device where the channels are 90 degrees out of phase with each other. This results in a resolution of four times the basic cycle of the flag. These quadrature outputs make it possible for the processor to determine the direction of penetrating member travel. Other suitable position sensors include capacitive encoders, analog reflective sensors, such as the reflective position sensor discussed above, and the like.

A coupler shaft guide 111 is disposed towards the proximal end 81 of the lancing device 80. The guide 111 has a guide lumen 112 disposed in the guide 111 to slidably accept the proximal portion 92 of the elongate coupler shaft 84. The guide 111 keeps the

elongate coupler shaft 84 centered horizontally and vertically in the slot 102 of the optical encoder 91.

Referring now to Figure 6, an embodiment of the present invention using an elastomeric actuator will now be described. The present invention consists of an electronic actuator 200 consisting of a soft elastomer sheet 202 with electrodes 204 applied to the opposing large surfaces. The geometry created is that of a capacitor. When electrical potential is applied to the electrodes, electrostatic forces attract the electrodes toward each other. As seen in Figure 7, the intervening soft elastomer is displaced by the electrodes, lengthening the elastomer. This displaced material 210 acts to elongate the elastomer/electrode assembly. Because the elastomer grows in length, it is desirable in one embodiment to construct the electrodes from a compliant material, such as carbon-loaded silicone (SRI patent), so they can conform to the elongated elastomer.

It has been observed that pre-stretching the elastomer (SRI) improves resistance to dielectric breakdown, and an extension of the operating voltage range. The actuator shown in Figure 8A consists of a rigid frame with a clamp at one end to hold the elastomer. At the other end of the frame a guide bearing holds an actuator shaft that is clamped to the other end of the elastomer. A pre-stretch spring tensions the elastomer. A controlled voltage source applies actuating voltage to the electrodes on the elastomer.

A second style of actuator shown in Figure 8B consists of a pre-tensioned diaphragm stretched over a chamber. An actuator shaft is attached to the center of the diaphragm, and may be guided by a bearing if needed. Electrodes applied to the diaphragm cause it to expand. To shape the diaphragm, and direct the resulting motion, a bias pressure is applied behind the diaphragm. The same function can be achieved by adding a bias spring to the actuation shaft.

Referring now to Figure 9, an important component of an actuator system is position feedback. A position signal can be obtained from an elastomeric actuator by measuring the capacitance of the actuator. This can be accomplished by imposing a sine wave, or pulse signal onto the DC drive voltage. The current resulting from this sensing signal is a measure of the capacitance of the actuator, and hence the deflection of the electrode plates.

An article titled Artificial Muscles in the October 2003 issue of Scientific American is incorporated herein by reference.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention.

5 For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or protective foil during launch). With any of the above embodiments, the penetrating
10 members may be a bare penetrating member during launch. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge may be in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes
15 described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The sensory material 14 may be deposited into the via holes 18. The conductor material may also be deposited into the via holes. The via holes may be formed by a variety of methods including micro drilling, laser drilling, plasma etching, or the like. The embodiments herein are adapted for use with lancing devices described in
20 U.S. Patent Applications Ser. No. 10/127,395 (Attorney Docket No. 38187-2551US) and U.S. Patent Applications Ser. No. 10/323,622 (Attorney Docket No. 38187-2606US). It should be understood that any of the inventions herein may be used in conjunction with devices disclosed in U.S. Patent Applications Attorney Docket No. 38187-2551, 38187-2608, and 38187-2662.

25 The publications discussed or cited herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed. All
30 publications, patents, and patent applications mentioned herein are incorporated herein by reference to disclose and describe the structures and/or methods in connection with which the publications are cited.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of
5 these smaller ranges may independently be included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either both of those included limits are also included in the invention.

Expected variations or differences in the results are contemplated in accordance
10 with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

- 1 1. A penetrating member actuator comprising:
2 a support structure;
3 a first electrode;
4 a second electrode;
5 an elastomeric material between said electrodes, wherein said material
6 elongates upon activation of the electrodes, causing a penetrating member to move.
- 1 2. The device of claim 1 further comprising a radial cartridge, said
2 material having a gripper positioned to engage penetrating members on said radial
3 cartridge.
- 1 3. The device of claim 1 further comprising a coupler in contact with
2 the material for coupling the penetrating member to the material.
1

ABSTRACT OF THE DISCLOSURE

A body fluid sampling device is provided. An actuation mechanism is described that utilizes the attractive electrostatic force between two charged plates of a capacitor to displace an elastomer material producing linear motion. Electrode spacing is
5 used to determine degree of actuation and to provide a position feedback signal.

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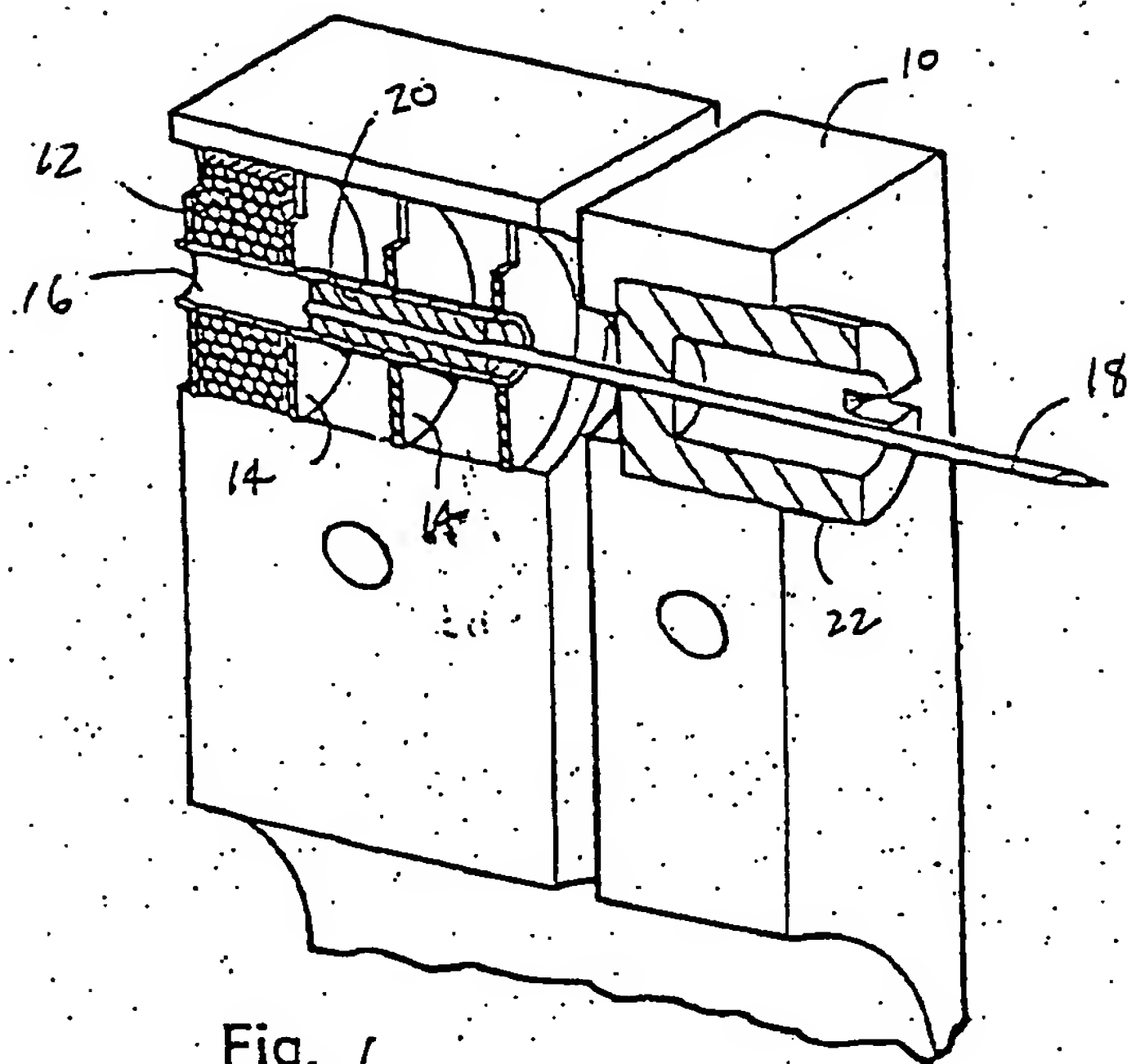


Fig. 1

DISPLACEMENT
(mm)

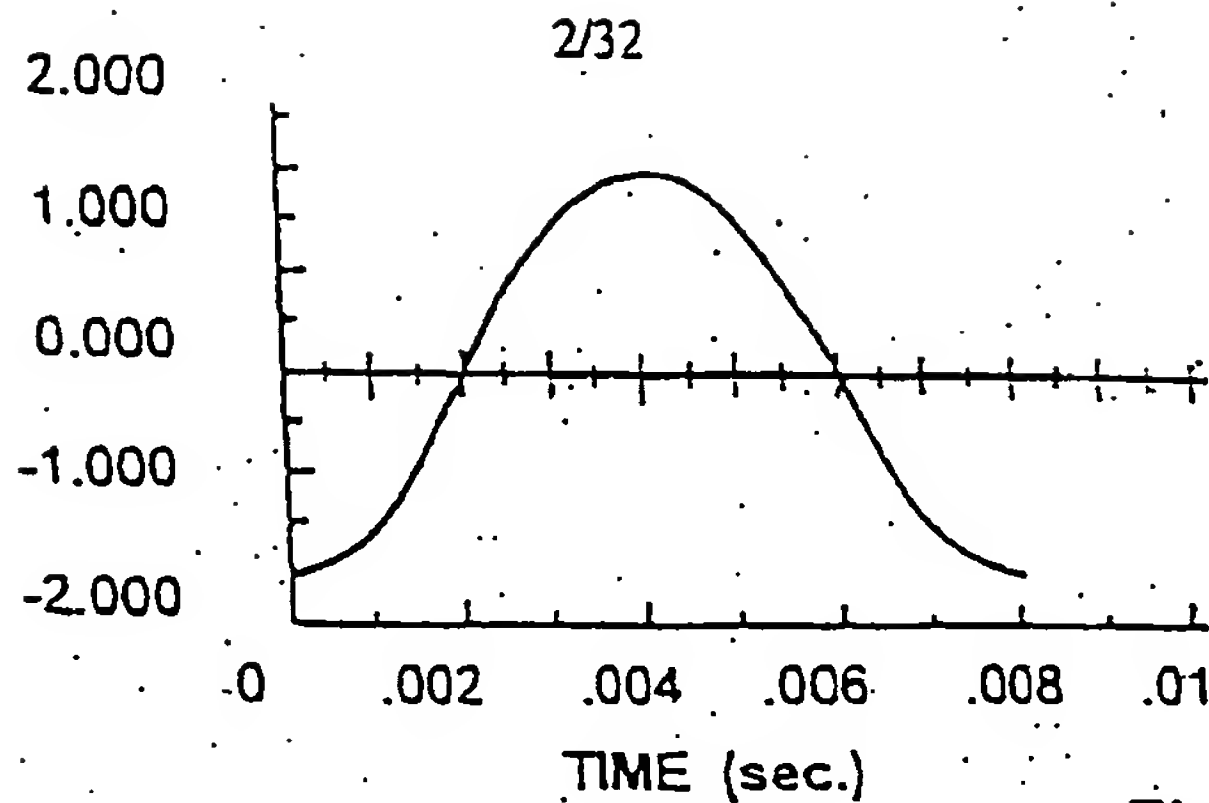


Fig. 24

VELOCITY
(m/sec.)

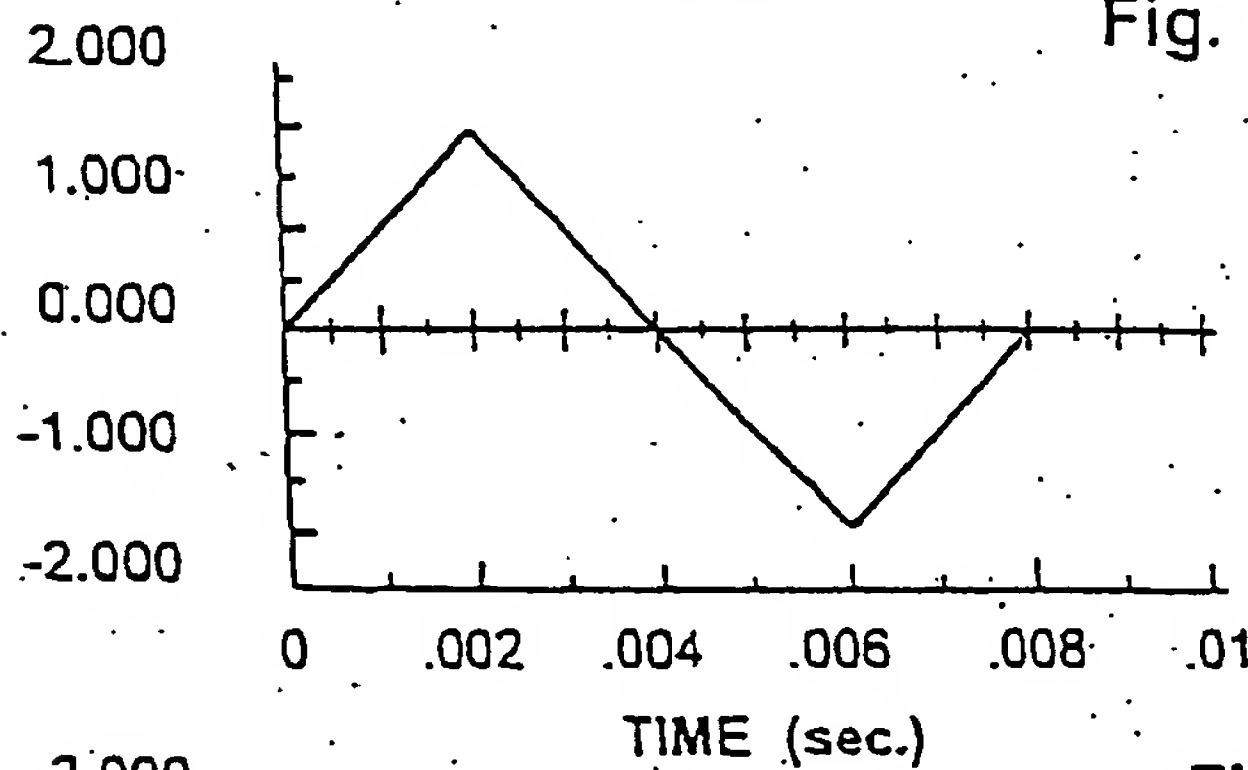


Fig. 29

DISPLACEMENT
(mm)

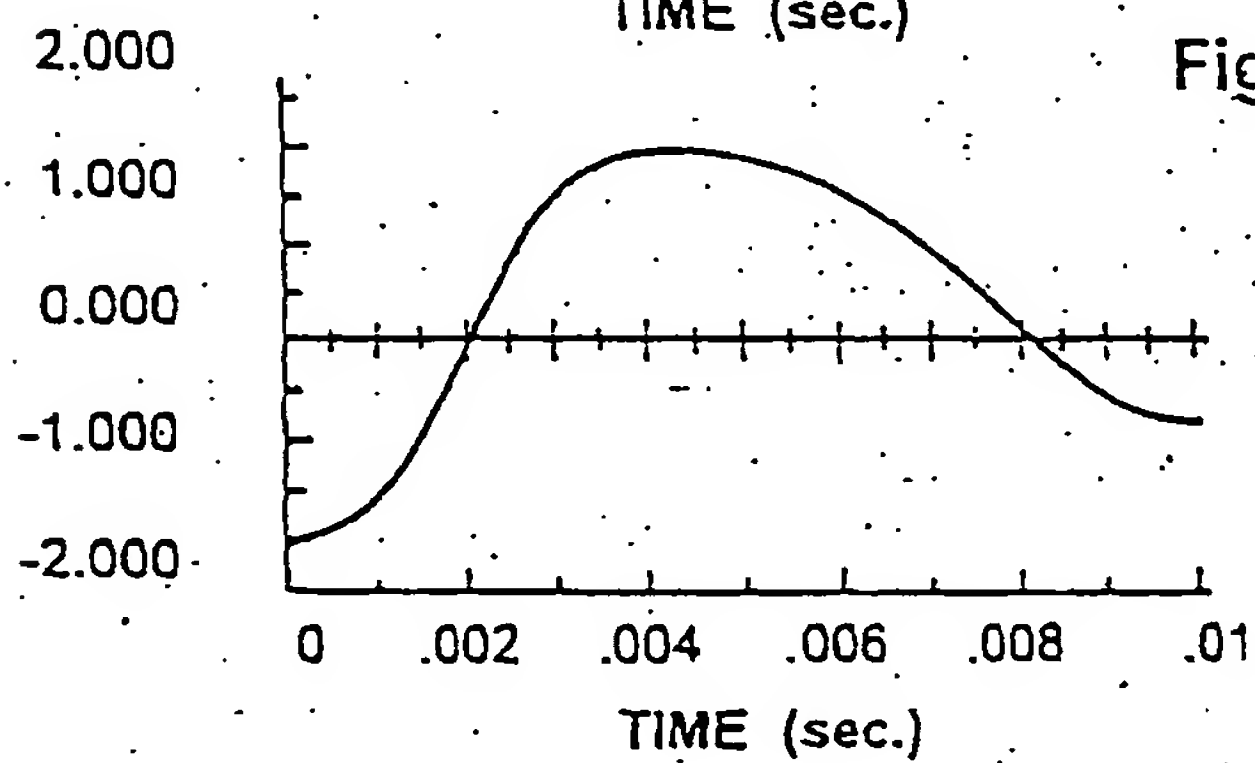


Fig. 2c

VELOCITY
(m/sec.)

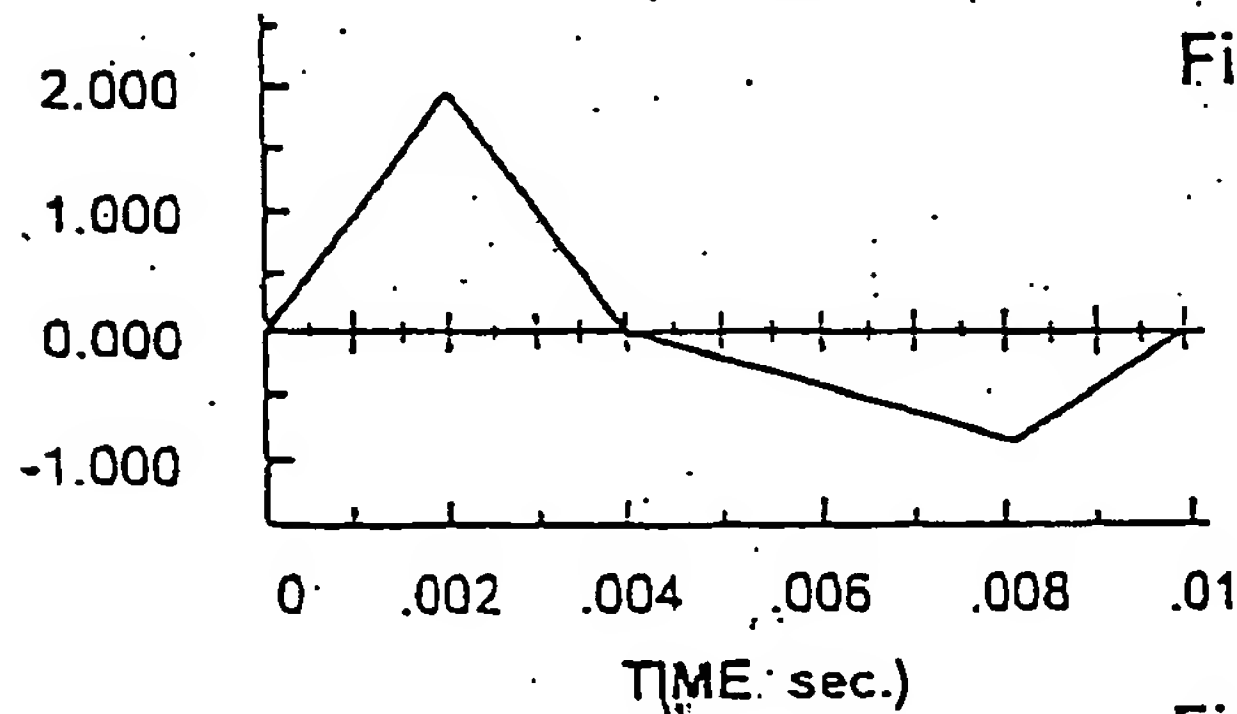


Fig. 2 Φ

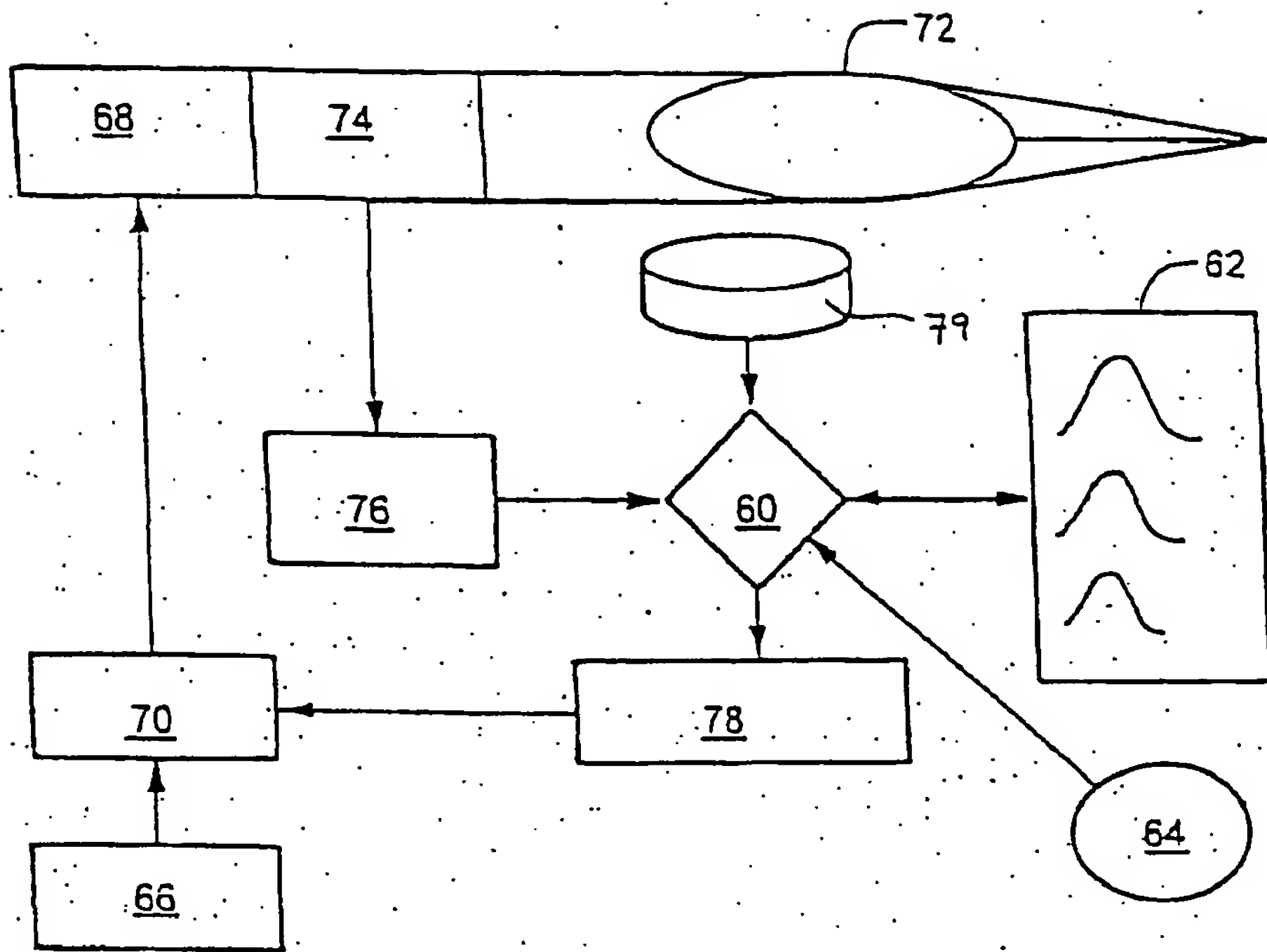


Fig. 3

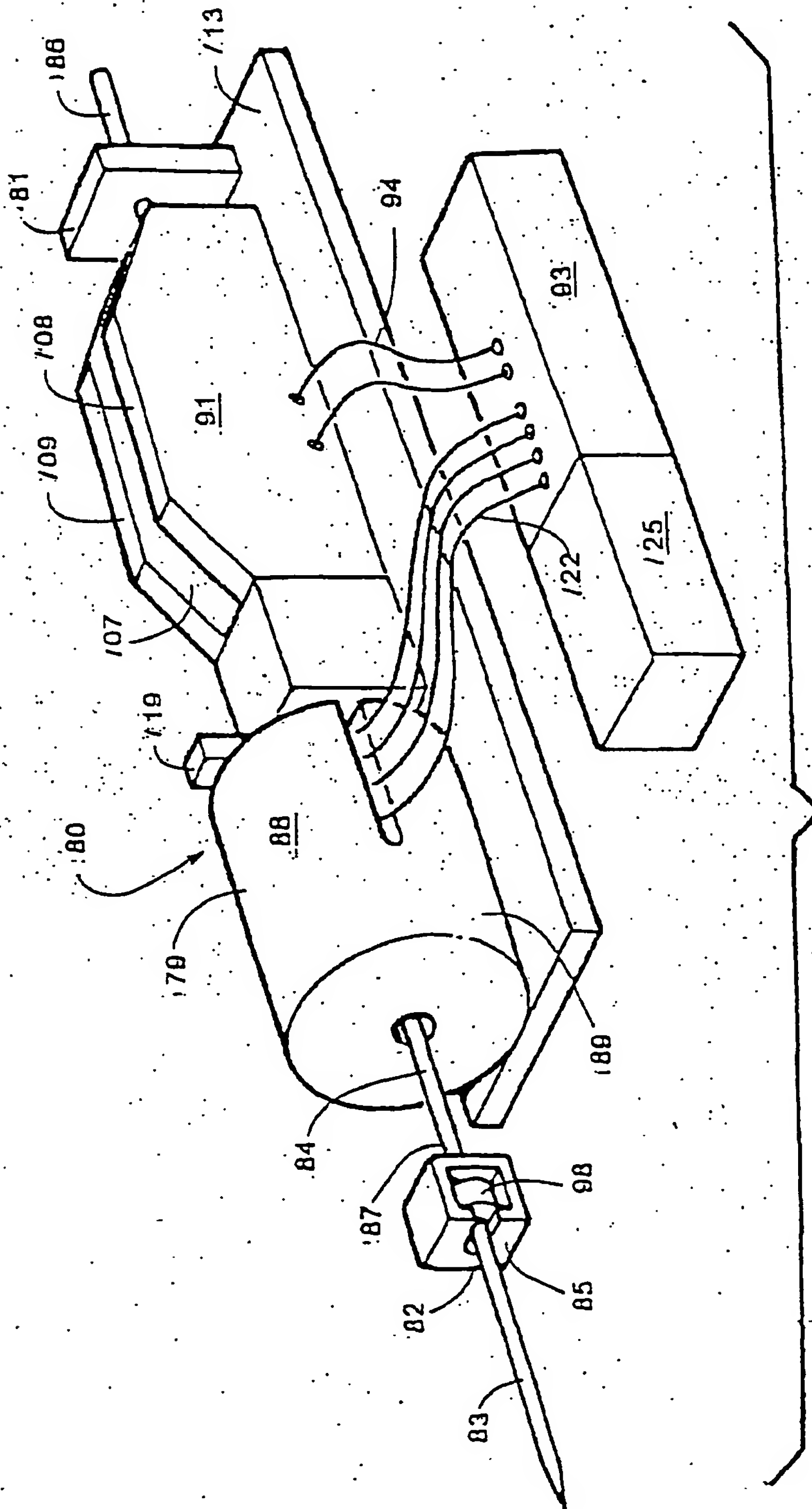


Fig. 4

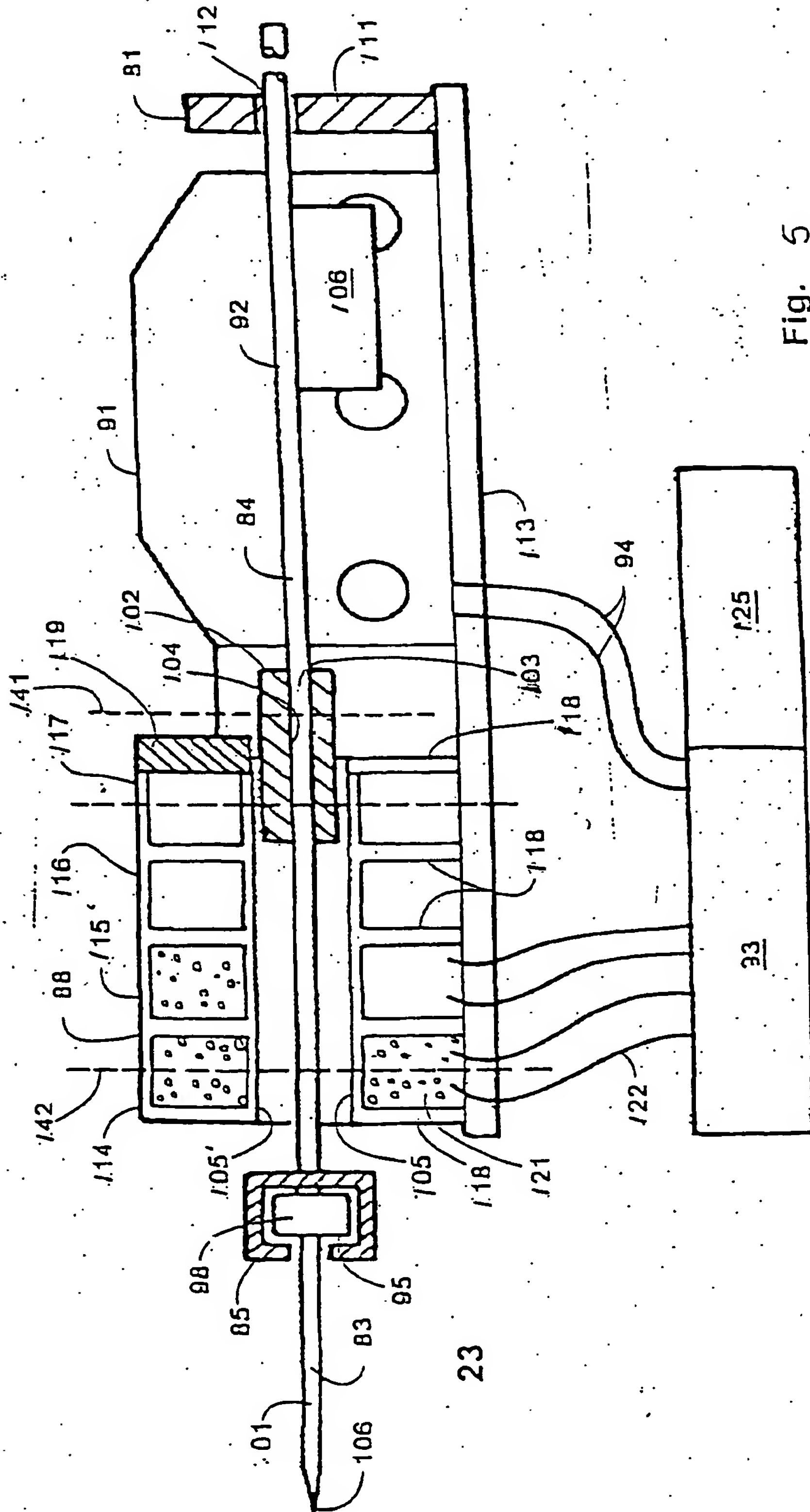


Fig. 5

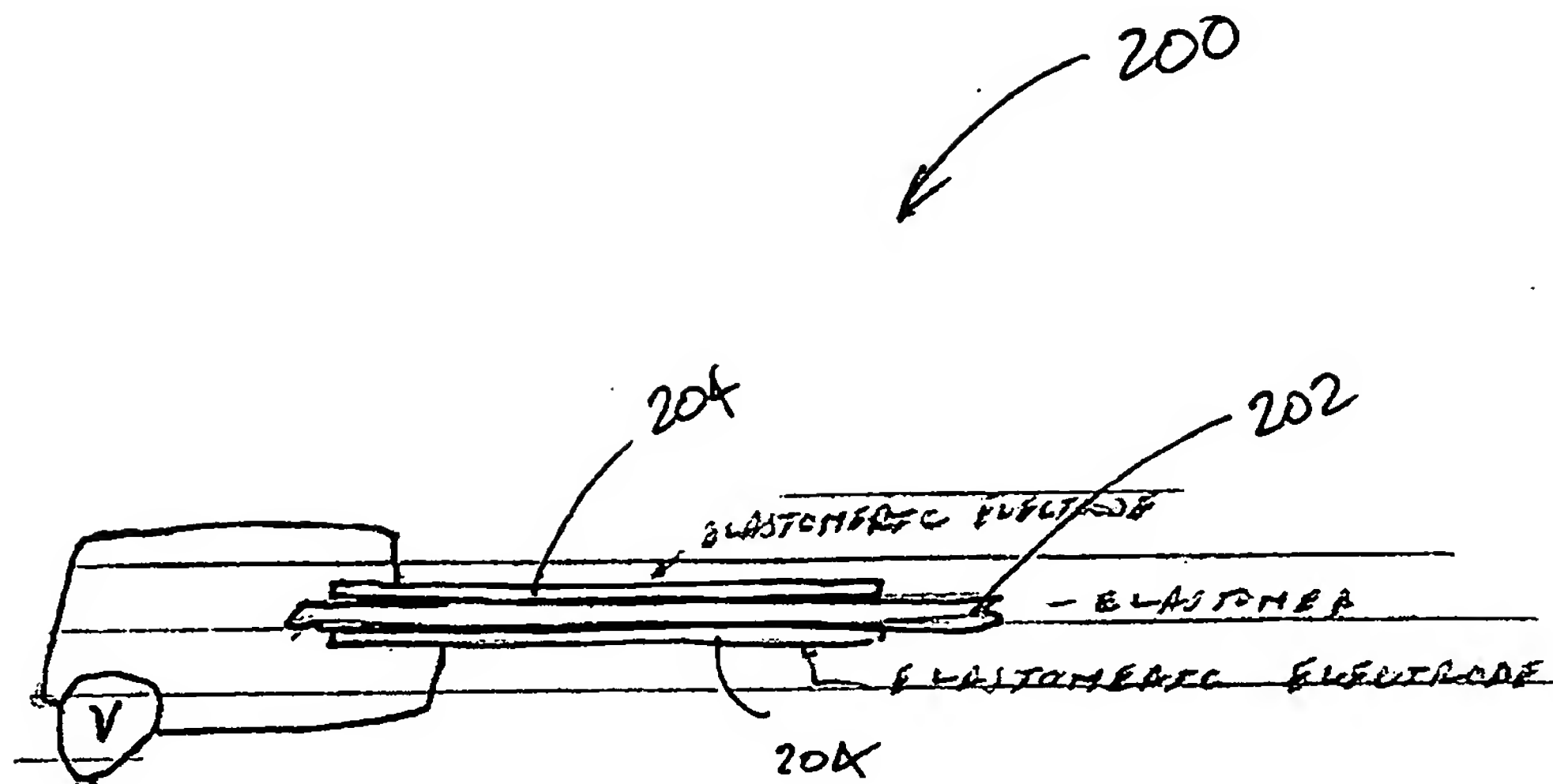


FIG-6

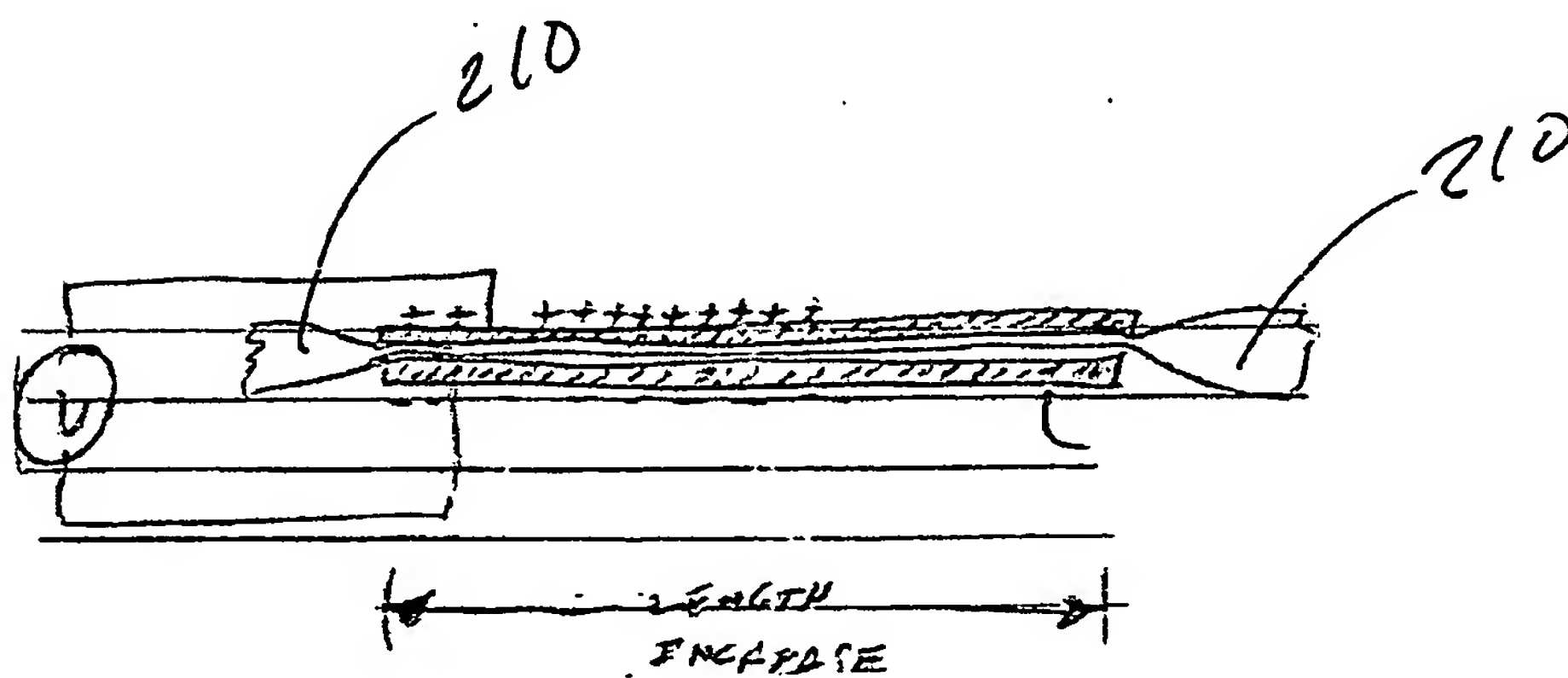


FIG-7

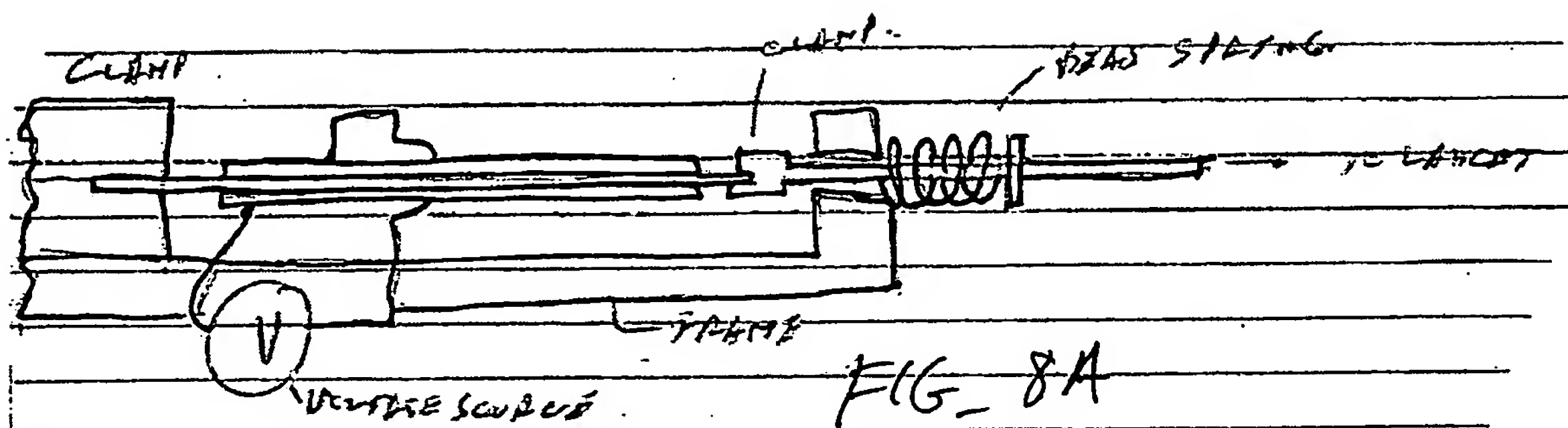


FIG-8A

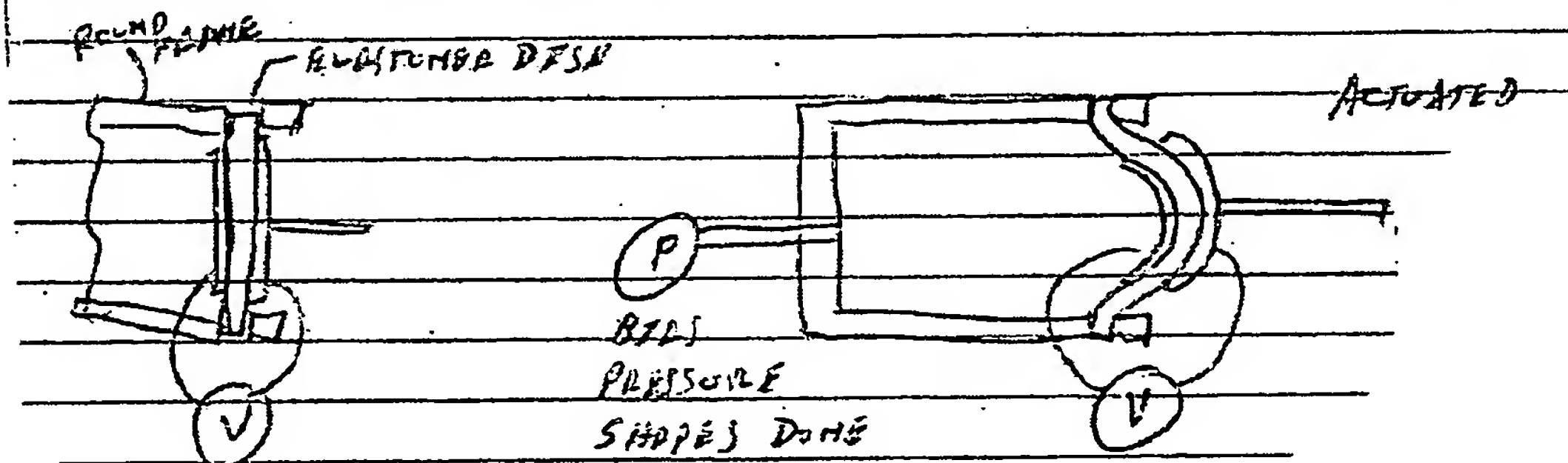
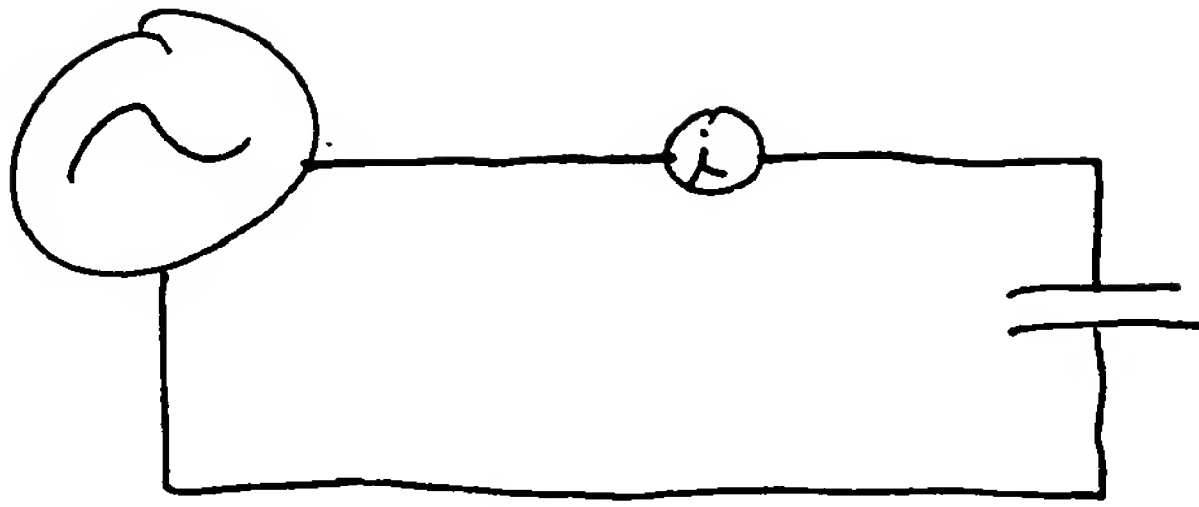


FIG-8B



FIG_9

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